REMARKS

Claims 124-130 and 143-149 are pending in the application. None of the claims are amended. Applicants provide a clean set of the claims for the examiner's convenience. The office action is discussed below:

Indefiniteness Rejection:

On page 2 of the office action, the examiner has withdrawn the indefiniteness rejection of claims 124-125, 128, and 130 in view of the response filed on April 16, 2009. Applicants thank the examiner for the withdrawal.

Response to Arguments and Anticipation Rejection:

On pages 2-4 and 5-6 of the Office Action, the examiner states that the arguments, filed on April 16, 2009, are not persuasive and maintained the rejection. Applicants respectfully disagree with the examiner and traverse the rejection. Applicants submit the examiner has repeated almost the same response (see pages 2-4 of the instant Office Action) as the Office Action of April 10, 2008 (see pages 2-5) and has not responded to the clarifications provided in the response filed on April 16, 2009, nor has addressed the declarations discussed therein (see pages 5-8 of the response).

With respect to inherent functions or properties in a disclosure the examiner refers to the same passage (see the Office Action of April 10, 2008 page 2) from the MPEP that: "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient".

Applicants submit the following in order to assist the examiner further distinguishing the claimed invention from the cited references.

Regarding the extrinsic evidence to establish the inherency and to make it clear

that the missing descriptive matter is present in the thing described in the reference, applicants submit that the specification provide full support regarding the inherent disclosure and the declarations as discussed previously further provide extrinsic evidence to establish the inherency of the claimed process steps, as are clear to one skilled in the art who are familiar with the van de Graaff generator. See Example 6 at pages 44-46, for example, although the thermal treatment was continued through the irradiation process of cross-linking, it is inherent that the UHMWPE is heated to melt after each passage through the conveyor belt, that is, after each cycle of irradiation, which includes heating in between two "melting" (that is, before and after each irradiation dose or a total dose of irradiation). Thus, it would be apparent to one skilled in the art reviewing the present specification and to those who is familiar with van de Graaff generator that specimens are taken out of the belt and reintroduced to continue on the irradiation process to achieve the desired total dose (in this case a total of 20 Mrad at a dose rate of 2.5 Mrad per pass, for example). It also would be apparent to one skilled artisan that after each passage the UHMWPE is taken out of the belt and melted when reintroduced to the belt to continue on heating (to melt) and irradiation cycle till the desired total dose is achieved. Applicants refer to the examiner's understanding in a related case that the irradiation was applied in a sequential manner in view of Dr. Muratoglu's declaration (see declaration at section 6, filed July 16, 2008 in US 11/006,786, copy attached) that clarifies a sequential process for preparing a medical implant by irradiating polymeric material, heating the irradiated polymer and cooling the radiation cross-linked material. The declaration thus provides extrinsic evidence to make it clear that the missing descriptive matter would be so recognized by persons of ordinary skill who are familiar with van de Graaff generator.

Therefore, the inherency of the claimed process was not established by "probabilities or possibilities" nor based on the mere fact that a certain thing may result from a given set of circumstances, as alleged by the examiner. In fact, it is clear to one skilled in the art, who is familiar with van de Graaff generator, that the recited steps are inherent to the claimed process as disclosed in the original specification.

Further, regarding the inherent features of the process steps, as recited in the

claims, in the absence of evidence to support such inherent features, for example, based on use of a van der Graff generator, applicants invite the examiner to consider the MPEP that states:

> "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).
>
> *See* MPEP §2163.02, Rev. 6, September 2007 at 2100-186.

Applicants submit that what is known in the field and accessible to all need not be repeated in the specification. *Falkner v. Inglis,* 448 F.3d 1357, 1365-68, 79 USPQ2d 1008 (Fed Cir. 2006).

As clarified previously and as evident from the declaration (see declaration at section 6, filed July 16, 2008 in US 11/006,786; copy attached), applicants also submit that the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicants were in possession of the invention as now claimed. Thus, it is not necessary that the claimed subject matter be described verbatim in the specification.

Applicants also draw the examiner's attention to the following relevant section of the recent version of the MPEP §2163.07(a) (Eighth Edition, Rev. 6, September 2007 at 2100-192) that dictates:

> "By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function,

> theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds,* 443 F.2d 384, 170 USPQ 94 (CCPA 1971), *In re Smythe,* 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973)."
>
> And that: "Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention."
>
> In this context, applicants refer the examiner, as discussed above that:
>
> "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement...."
>
> *See* MPEP §2163.02, Rev. 6, September 2007 at 2100-186.

On page 3 of the Office Action, the examiner states that Example 6 on pages 44-46 discloses heating a sample to 175°C, holding the temperature for 300 followed by irradiation using a van de Graaff generator. The examiner also states that the description on page 45 is that the electron beam entered the chamber through the thin foil at top and hit the surface with the hemispheric hole. The examiner interprets that the dose received by the specimen was such that a maximum dose of 20 Mrad was received approximately 5 mm below the surface of the polymer being hit by electrons. The examiner agreed that after irradiation the heating was stopped and the specimen cooled to room temperature. However, the examiner asserts that:

- There is no mention of a conveyor belt, cycles of radiation, heating to melt after passages through a conveyor belt;
- There is nothing to indicate that specimens were taken out of the belt and reintroduced to continue an irradiation process;
- There is no disclosure that irradiation is performed while the specimen is moving on a belt instead of being irradiated in place through the thin foil at top of the chamber;
- There is even less evidence that the specimens were taken out of a belt and melted when reintroduced to the belt to continue irradiation and heating; and
- The applicant has not provided any extrinsic evidence to support the argument that steps are inherently disclosed in the specification by mention

of use of a van de Graaff generator to irradiate UHMWPE.

Applicants refer to above claifications regarding the van de Graaff generator that, one skilled in the art who is familiar with van de Graaff generator would appreciate and understand that the process involves:

- a conveyor belt;
- cycles of radiation necessary to obtain a total dose as described in the specification;
- heating to melt after passages through the conveyor belt if the radiation is carried out on a heated specimen;
- the specimens must be taken out of the conveyor belt and reintroduced to continue on the irradiation process;
- the irradiation is performed while the specimen is moving on a belt when multiple doses are necessary to achieve a total absorbed dose (for example 20 MRads; and
- the specimens needs to be taken out of a belt to continue on heating to re-melt when reintroduced to the belt to continue irradiation and heating.

Applicants also refer to the above clarification and the specification that clearly disclose that the claimed steps are inherently disclosed in the specification by mention of use of a van de Graaff generator to irradiate UHMWPE (see for example, Example 6). To assist the examiner, applicants herewith provide photographs of a common van de Graaf generator (see attached Exhibits 1-4). Accordingly, applicants provided extrinsic evidences to support the arguments as filed on April 16, 2009.

On pages 3-4, bridging paragraph, the examiner agreed that the phrases "subsequent melting" and "remelting" both have the meaning heating above the melting temperature after an initial melting and irradiation. The examiner asserts that there is no recitation of a first step of melting UHMWPE before the step of irradiation and the step of heating at 150°C or above or of following the recited heating step with another irradiation step and another heating step before cooling and forming a medical implant. Applicants disagree with the examiner and submit, as clarified above, that it is inherent in the process that involves cycles of radiation and heating. Thus, the cycles involve

heating before and after irradiation, as one skilled in the art would understood.

In this context, applicants also refer to an expert opinion/evidence submitted in the related case (see U.S. App. No. 11/184,803, MERRILL *et al.,* declaration of Dr. Orhun Muratoglu, filed on September 22, 2008, pages 2-4 in sections 4, 7, and 8; copy attached) that this method is inherent to what is explicitly disclosed in the instant specification.

On page 4 of the Office Action, regarding the declaration pursuant to 37 C.F.R. § 1.131 evidencing completion of the claimed invention prior to January 20, 1995, the examiner asserts that the declaration supports that the methods comprising irradiation followed by "subsequent melting" were disclosed in Application Serial No 08/726,313, filed 10-02-1996 and in Application Serial No. 08/798,638, filed 02-11-1997. Applicants disagree with the examiner and point out that the present application has the same parent as the US Application Serial No. 10/197,263. The examiner has agreed that the phrases "subsequent melting" and "remelting" both have the meaning heating above the melting temperature after an initial melting and irradiation. As clarified above, the process involves remelting or heating above 150°C, which is explicitly and/or inherently disclosed in the original specification. Therefore, the declaration in the parent case shows that the completion of the disclosed investigation is prior to January 20, 1995, which is also applicable to the instantly claimed subject matter.

Applicants further refer to the declaration Exhibit 1, pages 1-2, Exhibit 3, Experiment 2, for various methods of irradiations and subsequent heating steps, for example, that provides evidence of reduction to practice of the disclosed "MIR" and "IR-SM" methods before January 20, 1995.

In view of the above clarifications, applicants request withdrawal of the rejection.

Claim Interpretation and Effective Filing Date:

On pages 4-5 of the Office Action, the examiner interprets claims 124-130 and 143-149 to recite that the irradiation and subsequent melting method ("IR-SM") first disclosed in SN 08/726,313, filed October 2, 1996. Thus, the examiner opined that

claims 124-130 and 143-149, wherein the irradiation step precedes the melting step have an effective filing date of October 2, 1996, and February 13, 1996 is the filing date of the priority application SN 08/600,744. Therefore, the examiner considers that the earliest effective filing date of the instant claims wherein the method steps comprise irradiation followed by melting the irradiated UHMWPE is considered to be the October 2, 1996 filing date of SN 08/726,313. Applicants respectfully disagree with the examiner and traverse the rejection. Applicants submit the examiner has repeated almost the same response (see page 5 of the instant Office Action) as the Office Action of April 10, 2008 (see page 5) and has not responded to the clarifications provided in the response filed on April 16, 2009, nor has addressed the declarations discussed therein (see pages 5-8 of the response).

Applicants also submit, as discussed above and as evidenced by the declaration and the Exhibits, that the instantly claimed embodiment wherein irradiation is followed by melting, i.e. "IR-SM", was reduced to practice prior to January 20, 1995.

Regarding the priority claim, applicants also refer to the Rule 1.131 Declaration of Merrill *et al.*, filed June 8, 2007, in a related case U.S. App. No. 10/696,362 (MERRILL *et al.*, copy attached). In the declaration Professor Merrill clarified that the polyethylene is first melted and then irradiated, which provides the evidence of reduction to practice of a method wherein irradiation is followed by subsequent melting or re-melting. Applicants also refer the examiner to the evidence in the Declaration of Merrill *et al.*, filed June 8, 2007 under Rule 1.131, which the examiner agreed (see Office Action of September 7, 2007, page 2, in the US application serial no. 10/696,362) that the evidence presented shows reduction to practice of the instantly claimed methods before January 20, 1995. It also was evident that the polyethylene was first melted and then irradiated (see the Declaration of Merrill *et al.*, sections 10-11 and item b of Exhibit 1, for example), which sufficiently provides the evidence of reduction to practice of the claimed method. Hence, a method that involves irradiation is followed by subsequent melting/re-melting and multiple doses or passes of radiation was reduced to practice before January 20, 1995.

On page 5 of the Office Action, the examiner also asserts that claims 128-129

are not supported by the disclosure of SN 08/600,744, does not disclose the swell ratio or degree of oxidation of the crosslinked UHMWPE, thus, according to the examiner claims 128-129 are not entitled to the February 13, 1996. Applicants disagree and refer to the original specification, see for example, Example 4, Tables 2 and 6; and Example 11, Tables 8 and 11 for support.

In view of the above clarifications, applicants submit that Shen *et al.* (the '900 patent) and Hyon *et al.* (the '626 patent), are not prior art to the claimed invention. Accordingly, withdrawal of the anticipation rejection is solicited.

Double Patenting Rejections:

On pages 7-9 of the office action, the examiner has maintained the provisional obviousness-type double patenting rejection of the claims and alleged as being directed to the same invention as the claims of co-pending application serial nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089, and 10/197,263.

Applicants reiterate, since a notice of allowability has not been issued for any of the application serial nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089, and 10/197,263, the merits of this provisional rejection need not be discussed with the examiner at this time. *See* MPEP § 822.01.

REQUEST

Applicants submit that claims 124-130 and 143-149 are in condition for allowance, and respectfully request favorable consideration to that effect so that an interference can be declared with applicants as the senior party by virtue of the priority afforded by the priority applications. The examiner is invited to contact the undersigned at (202) 628-6600 should there be any questions.

Respectfully submitted,

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Date

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